From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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### PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing (day/month/year)

26.01.2006

Applicant's or agent's file reference 6395-66078-02

IMPORTANT NOTIFICATION

International application No. PCT/US2004/032378

Applicant

International filing date (day/month/year)

01.10.2004

Priority date (day/month/year) 17.10.2003

THE GOVERNMENT OF THE UNITED STATES OF AMERICA..et

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:



European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465

- 0 Tx: 523656 epmu d Tel. +49 89 2399-2557

**Authorized Officer** 

Marnell, J







## **PCT**

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FOR FURTHER ACT		rion :	See Form PCT/IPEA/416	
6395-66078-02				
International application No. International filing date (d PCT/US2004/032378 01.10.2004		ay/month/year)	Priority date (day/month/year) 17.10.2003	
International Patent Classification (IPC) or national classification and IPC				
G01N1/24, G01N15/00				
Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICAet				
<ol> <li>This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</li> </ol>				
2. This REPORT consists of a total of 7 sheets, including this cover sheet.				
3. This report is also accompanied by ANNEXES, comprising:				
a. 🛛 sent to the applicant and to the International Bureau) a total of 4 sheets, as follows:				
sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).				
Shoots which supersede earlier sheets, but which this Authority considers contain an amendment that goes			ders contain an amendment that goes	
beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.				
b. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).				
Box Relating to Sequence	e Listing (see Section 802	of the Administrative	instructions).	
		•		
4. This report contains indications relating to the following items:				
☑ Box No. I Basis of the opinion				
☐ Box No. II Priority	•			
l .		d to novelty, inventive	step and industrial applicability	
Box No. IV Lack of unity o				
Box No. V Reasoned state applicability; ci	tement under Article 35(2) itations and explanations	) with regard to noverty supporting such stater	r, inventive step or industrial nent	
☐ Box No. VI Certain docum				
☐ Box No. VII Certain defects			eracija i distribution di series di	
Box No. VIII Certain observ	Box No. VIII Certain observations on the international application			
Date of submission of the demand		Date of completion of th	is report	
17.08.2005	·	26.01.2006		
Name and mailing address of the international		Authorized Officer		
preliminary examining authority:			an i	
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Tel. +49 89 2399 - 0 Tx: 523 Fax: +49 89 2399 - 4465	ооо ерти ч	Telephone No. +49 89	2399-5666	
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# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

3015/5048

International application No. PCT/US2004/032378

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	Box No. I Basis of the report				
1.	With regard to the <b>language</b> , this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.				
		ations from the original language into the following language, nslation furnished for the purposes of:			
	☐ international search (und☐ publication of the internat☐ international preliminary of the interna	r Rules 12.3 and 23.1(b)) onal application (under Rule 12.4) xamination (under Rules 55.2 and/or 55.3)			
2.	Nith regard to the <b>elements*</b> of the international application, this report is based on <i>(replacement sheets whic</i> have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):				
	Description, Pages				
	1-23	as originally filed			
	Claims, Numbers				
	1-6, 15-27	as originally filed			
	7-14, 28-38	received on 09.01.2006 with letter of 05.01.2006			
	Drawings, Sheets	<u>:</u>			
	1/10-10/10	as originally filed			
	a sequence listing and/or an	related table(s) - see Supplemental Box Relating to Sequence Listing			
3.	.   The amendments have resu	ed in the cancellation of:			
	<ul><li>the description, pages</li><li>the claims, Nos.</li></ul>				
	the drawings, sheets/figs				
	☐ the sequence listing (spe ☐ any table(s) related to se				
4.	.   This report has been establi	hed as if (some of) the amendments annexed to this report and listed below			
	had not been made, since they h Supplemental Box (Rule 70.2(c))	ave been considered to go beyond the disclosure as filed, as indicated in the			
	<ul><li>the description, pages</li><li>the claims, Nos.</li></ul>				
	☐ the drawings, sheets/figs	en de la companya de La companya de la co			
	☐ the sequence listing (spe ☐ any table(s) related to se	cify):			
		me or all of these sheets may be marked "superseded."			
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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/US2004/032378

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

No:

Claims

1,2,4,8-9,22,27-29

Inventive step (IS)

Yes: Claims

12-21,34-38

No: Claims

3,5-7,10-11,23-26,30-33

Industrial applicability (IA)

Yes: Claims

1-38

No: Claims

2. Citations and explanations (Rule 70.7):

see separate sheet

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.

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1. Reference is made to the following documents:

D1: US-A-4 941 899 (LIU ET AL) 17 July 1990 (1990-07-17)

### Objections pursuant to Article 33(2) PCT (Novelty)

- 2. Document D1 discloses an apparatus for collecting airborne particles comprising
  - a collection vessel (23) with an open end and a closed end,
  - a collection vessel retaining member (17,25) adapted to be removably coupled to the collection vessel,
  - an air-inlet conduit (15) in the retaining member for permitting air to flow into the collection vessel through the open end,
  - an air-outlet conduit (19) for permitting air to exit the collection vessel; wherein
  - the inlet and outlet conduits are configured in such a way that the air flowing into collection vessel coupled to the retaining member establishes a cyclonic flow path separating the airborne particles from the air.

See Figure 1 and column 2, lines 21-51.

Accordingly, the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

It should be noted that, although it has no been explicitly disclosed in D1 that the cyclonic flow path extends into the collection vessel (23), it is implicitly clear that the cyclonic flow path starting in the retaining member (17) does not suddenly stop at the point where the collection vessel (23), having the same measurements as the retaining member (17), starts but rather extends in to the collection vessel, see Figure 1.

- 2.1 The air-inlet conduit (15) according to D1 is non-orthogonal to the plane that is parallel to the open and of the collection vessel (23), see Figure 1. Accordingly, the subject-matter of claim 2 is not new in the sense of Article 33(2) PCT.
- 2.2 The air-outlet conduit (19) according to D1 extends generally axially relative to the

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### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

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collection vessel (23), see Figure 1. Accordingly, the subject-matter of claim 4 is not new in the sense of Article 33(2) PCT.

- 2.3 According to D1, the collection vessel (23) is a first collection vessel, the air-inlet conduit (15) is a first air-inlet, the air-outlet conduit (19) is a first air-outlet; and
  - the retaining member (17,25) is adapted to be removably coupled to a second collection vessel (30),
  - the retaining member (17,25) comprises a second air-inlet (26) and a second air-outlet (38), the first air-outlet (19) being connected to the second air-inlet (26), in such a way that
  - the air flowing from the first air-outlet (19) flows into the second collection vessel (30) through the second air-inlet (26); wherein
  - the second air-inlet and air-outlet are configured in such a way that a cyclonic flow separating the airborne particles from the air is established.

See Figure 3, and column 2, line 52 - column 3, line 51.

Accordingly, the subject-matter of claim 8 is not new in the sense of Article 33(2) PCT.

- 2.4 According to D1, the particles deposited in the first collection vessel (23) are generally larger than the particles deposited in the second collection vessel (30), see column 2, lines 49-51. Accordingly, the subject-matter of claim 9 is not new in the sense of Article 33(2) PCT.
- 3. Claim 22 defines a method analogue to the apparatus of claim 1. Therefore, the objections under item 2 above apply *mutatis mutandis* to the subject-matter of claim 22 which, accordingly, is not new in the sense of Article 33(2).
- 3.1 Claim 27 defines a method analogue to the apparatus of claim 8. Therefore, the objections under item 2.3 above apply *mutatis mutandis* to the subject-matter of claim 27 which, accordingly, is not new in the sense of Article 33(2).
- 3.2 Claim 28 defines a method analogue to the apparatus of claim 9. Therefore, the objections under item 2.4 above apply *mutatis mutandis* to the subject-matter of claim

28 which, accordingly, is not new in the sense of Article 33(2).

3.3 According to D1, analysis is performed on the particles collected in the collection vessel. Accordingly, the subject-matter of claim 29 is not new in the sense of Article 33(2) PCT.

### Objections pursuant to Article 33(3) PCT (Inventive Step)

4. Dependent claims 3, 5-7, 10-11 and 23-26, 30-33 would appear to define minor modifications to the apparatus or method respectively. These modifications are either well known in the art or merely workshop modifications. Hence, the person skilled in the art would carry them out in accordance with the circumstances without having to exercise any inventive skill whatsoever. Accordingly, the subject-matter of the above-mentioned claims does not contain an inventive step in the sense of Article 33(3) PCT.

#### Further observations considering Article 33(2) and 33(3) PCT

5. The subject-matter of claim 12 differs from that disclosed in the closest prior art D1 (see above) in that the collection vessel comprises a microcentrifuge tube having an open end that is orthogonal to a line extending longitudinally with respect to the tube and in that the air-inlet conduit is non-orthogonal and non-parallel to the plane of the open end of the tube.

Accordingly, the subject-matter of claim 12 is new in the sense of Article 33(2) PCT.

The technical problem addressed by the above mentioned difference is to make the collecting apparatus compatible with commonly used laboratory analyzers.

The above mentioned technical problem has not been recognised in the available prior art, nor have the technical features required to solve it been disclosed or hinted at. Accordingly, the subject-matter of claim 12 would appear to contain an inventive step in the sense of Article 33(3) PCT.

Furthermore, the subject-matter of claim 34, defining a method analog to the

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

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apparatus of claim 12, would appear to fulfill the requirements of Article 33(2) and 33(3) PCT with respect to novelty and inventive step.

### Further observations on the form and content of the international application

- 6. In addition to the objections above, the following should be noted.
- 6.1 Independent apparatus claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 6.2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor are these documents identified therein.
- 6.3 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 6.4 The vague and imprecise statement in the description on page 23 implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them.
- 6.5 Claims 32 and 33 seek to define the method by features of the collected particles. As these particles are not a part of the method, the method should not have been defined by their features. Accordingly, the subject-matter of claims 32 and 33 does not fulfill the requirements of Article 6 PCT with respect to clarity.

an air-inlet conduit for conducting air into the collection vessel, the air-inlet conduit extending at an angle with respect to a plane that is parallel to the open end, the air-inlet conduit being non-orthogonal and non-parallel to said plane; and

an air-outlet conduit for conducting air out of the collection vessel;

wherein the air-inlet conduit and the air-outlet conduit are situated to cause air flowing through the collection vessel to create a vortex, thereby causing airborne particles to separate from the air flowing through the collection vessel.

#### 13. The apparatus of claim 12 wherein:

the collection vessel is a first collection vessel, the air-inlet conduit comprises a first air-inlet conduit, and the air-outlet conduit comprises a first air-outlet conduit; and the apparatus further comprises:

a second collection vessel;

a second air-inlet conduit in fluid communication with the first air-outlet conduit so that air flowing through the first air-outlet conduit is conducted into the second collection vessel through the second air-inlet conduit, the second air-inlet conduit being non-orthogonal to a line extending longitudinally with respect to the second collection vessel; and

a second air-outlet conduit for conducting air out of the second collection vessel;

wherein the second air-inlet conduit and the second air-outlet conduit are situated to cause air flowing through the second collection vessel to create a vortex, thereby causing airborne particles to separate from the air flowing through the second collection vessel.

14. The apparatus of claim 13, wherein the first collection vessel is supported in the same orientation as the second collection vessel.

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- The method of claim 27, wherein the particles collected in the second collection 28. vessel are generally smaller than the particles collected in the first collection vessel.
- 5 29. The method of claim 27, further comprising performing an analysis on the particles that are collected in the second collection vessel.
  - 30. The method of claim 27, wherein the analysis is performed while the particles are still in the second collection vessel.
  - 31. The method of claim 22, wherein the analysis of the particles is performed while air is flowing through the collection vessel.
    - 32. The method of claim 22, wherein the particles are bioaerosols.
  - 33. The method of claim 22, wherein the particles collected in the collection vessel are approximately equal to and greater than 2 microns in size.
- 34. A method for collecting airborne particles for analysis, the method comprising: flowing air through the open end of a microcentrifuge tube along a flow path in a direction that extends generally tangentially with respect to an inner surface of the microcentrifuge tube, the open end being orthogonal to a line extending longitudinally with respect to the tube, the flow path being non-orthogonal and non-parallel to a plane defined by the open end, wherein the air flowing through the microcentrifuge tube establishes a cyclone; and 25 separating airborne particles from the air flowing through the microcentrifuge tube.
  - 35. The method of claim 34, wherein the air flowing through the microcentrifuge tube establishes a reverse-flow cyclone.

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- 36. The method of claim 34, wherein the air flowing into the microcentrifuge tube is conducted through an inlet conduit of an air-flow fitting coupled to the microcentrifuge tube, and wherein air flowing out of the microcentrifuge tube is conducted through an outlet conduit of the air-flow fitting.
- 37. The method of claim 34, wherein air flowing outwardly from microcentrifuge tube is conducted into a secondary collection vessel to further separate airborne particles from the air flow.

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38. The method of claim 33, further comprising performing an analysis on the particles that are separated from the air flowing through the microcentrifuge tube.